IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9072

Bartle, J. May 22, 2013

Rita A. Stone ("Ms. Stone" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In August, 2004, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Arnold B. Meshkov, M.D., F.A.C.C. Dr. Meshkov is no stranger to this litigation. According to the Trust, he has signed at least 124 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated December 6, 2001, Dr. Meshkov attested in Part II of Ms. Stone's Green Form that she suffered from moderate aortic regurgitation and a reduced ejection fraction in the range of 40% to 49%.[3] Based on such findings,

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2. (...continued)
serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. Dr. Meshkov also attested that claimant suffered from mild
(continued...)

claimant would be entitled to Matrix A-1, Level II benefits in the amount of $512,025.[4]

In the report of the claimant's echocardiogram, the reviewing cardiologist, Allen A. Nimetz, M.D., stated that claimant had "[n]ormal left ventricular systolic function" with an ejection fraction of 60%. Under the Settlement Agreement, an ejection fraction is considered reduced for purposes of an aortic valve claim if it is measured as less than 50%. See Settlement Agreement § IV.B.2.c.(2)(a)iii).

In March, 2006, the Trust forwarded the claim for review by Alan J. Bier, M.D., one of its auditing cardiologists. In audit, Dr. Bier concluded that there was no reasonable medical basis for Dr. Meshkov's finding that claimant had a reduced ejection fraction. Dr. Bier explained:

> The left ventricle is vigorous and symmetrical in all views. Clearly an ejection fraction of >60%, nevertheless 49%. The [echocardiogram] report, included in the medical records describes "normal left ventricular systolic function" and reports an ejection fraction of 60%, a number I still

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3. (...continued)
mitral regurgitation and New York Heart Association Class I Functional symptoms. These conditions are not at issue in this claim.

4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the aortic valve if he or she is diagnosed with moderate or severe aortic regurgitation and one of three complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(a). As the Trust does not contest the attesting physician's finding of moderate aortic regurgitation, the only issue is whether claimant has a reduced ejection fraction, which is one of the complicating factors needed to qualify for a Level II claim.

> think is slightly low, but much closer to reality than 40-49%.

Based on Dr. Bier's finding that claimant did not have a reduced ejection fraction, the Trust issued a post-audit determination denying Ms. Stone's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[5] In contest, claimant submitted a letter from Dr. Meshkov, wherein he stated that he re-reviewed Ms. Stone's echocardiogram and again concluded it demonstrated a reduced ejection fraction. Dr. Meshkov explained:

> I strongly disagree with Dr. Bier's assessment of the overall left ventricular systolic function demonstrated on this echocardiogram. The determination of left ventricular systolic function by echocardiography depends upon several factors including technical quality of the study, the ability to look at left ventricular function in different anatomic plans, and the experience of the echocardiographer in determining this study.
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> Although multiple attempts have been made to quantitate left ventricular systolic function by echocardiography, all of these techniques have significant limitations. One of the most important limitations is that in the presence of abnormal systolic function of the left ventricle, regional differences appear in left ventricular function, and one

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5. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Stone's claim.

> therefore must assess all 4 orthogonal views of the left ventricle before arriving at a decision about overall left ventricular ejection fraction. Interpretation of a technically good study by an experienced echocardiographer correlates well to even the most accurate other technologies used to determine left ventricular systolic function.
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> ....
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> In reviewing Ms. Stone's echocardiogram, if one looks at the long axis view the left ventricle clearly is dilated and hypokinetic in this view indicating that the probable overall left ventricular ejection fraction is less than 50%. However, in the short axis view of the left ventricle it appears to be of normal size and overall contractile function when viewed from the base or the upper portion of the heart. However, it is very clear that there is significant mid to distal hypokinesis of the left ventricle seen on multiple 4 chamber and 2 chamber views of the left ventricle. This type of dysfunction and elongation of the heart is typical from chronic aortic regurgitation. I reaffirm my opinion as stated previously that the overall left ventricular ejection fraction is between 40 and 49%.

The Trust then issued a final post-audit determination, again denying Ms. Stone's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the Court for issuance of an Order to show cause why Ms. Stone's claim should be paid. On October 19, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6619 (Oct. 19, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on December 28, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[6] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that she had a reduced ejection fraction. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such

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6. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Stone argues that there is a reasonable medical basis for her attesting physician's representation that she had a reduced ejection fraction. According to Ms. Stone, Dr. Meshkov supported his opinion with "evidence of dilation and hypokinesis of the left ventricle in the long axis view which indicates an overall ejection fraction of less than 50%," while Dr. Bier "disregards this evidence which would support Dr. Meshkov's opinions." In addition, claimant contends that measuring the left ventricular ejection fraction is highly subjective because it is estimated based on an echocardiogram. Finally, Ms. Stone asserts that the auditing cardiologist cannot merely disagree with the attesting physician and cannot substitute his or her own clinical judgment for that of the attesting physician.

In response, the Trust argues that Dr. Meshkov's supplemental opinion does not refute Dr. Bier's specific finding that claimant's "left ventricle is vigorous and symmetrical in all views." The Trust also contends that Dr. Meshkov did not offer any explanation for the discrepancy between his representation that Ms. Stone had a reduced ejection fraction in the range of 40% and 49% and the notation in the echocardiogram

report that Ms. Stone's ejection fraction was 60%. Finally, the Trust asserts Dr. Bier provided a sufficient explanation for his findings.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's representation that Ms. Stone had a reduced ejection fraction. Specifically, Dr. Vigilante stated:

> The left ventricle was normal in size and had excellent contractility without regional wall motion abnormalities. There was normal wall motion noted in the parasternal long axis view, parasternal short axis view, apical four chamber view, and apical two chamber view. There was normal thickening of all segments of the left ventricle. Visually, the left ventricular ejection fraction was greater than 60%. I digitized those cardiac cycles in the apical four chamber and apical two chamber views in which the left ventricular endocardium could be well defined and the left ventricle was on-axis. I then traced the left ventricular end diastolic and left ventricular end systolic dimensions and determined the areas in the apical four chamber and apical two chamber views. I determined the left ventricular ejection fraction by Simpson's method. The left ventricular ejection fraction was 66%. The left ventricular ejection fraction never came close to approaching 50%. In the long axis view, the left ventricle clearly is normal in size and contractility. There was no evidence of hypokinesis. Dr. Meshkov's assessment clearly was inaccurate. This ejection fraction corresponds to the finding of a normal left ventricular ejection fraction by both the original echocardiographer and the Auditing Cardiologist.
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> ....

> In response to Question F.8[.], there is no reasonable medical basis for the Attesting Physician's answer of ejection fraction in the range of 40%-49%. That is, the ejection fraction is 66% and clearly much higher than 49% with comments as above. An echocardiographer could not reasonably conclude that an ejection fraction of 40%-49% was present on this study even taking into account inter-reader variability.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. As an initial matter, we do not agree with claimant that the supplemental opinion of Dr. Meshkov provides a reasonable medical basis for his representation that Ms. Stone had a reduced ejection fraction. Dr. Meshkov stated that while claimant's left ventricle appeared to be of normal size and contractile function when viewed in the short axis view, it was dilated and hypokenetic in the long axis view and there was significant mid to distal hypokinesis of the left ventricle seen in the multiple 4-chamber and 2-chamber views. Dr. Bier, however, explained that "[t]he left ventricle [was] vigorous and symmetrical in all views." Dr. Bier further noted that the reviewing cardiologist, Dr. Nimetz, also found a normal ejection fraction of 60%.[7] In addition, Dr. Vigilante reviewed claimant's echocardiogram and concluded that it demonstrated an ejection fraction greater than 60%. Dr. Vigilante specifically determined that the left ventricle was

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7. For these reasons, we reject claimant's argument that the auditing cardiologist merely disagreed with the attesting physician or substituted his own clinical judgment for that of the attesting physician.

of normal size and contractility in the long axis view and that there was no evidence of hypokinesis.[8] Thus, Dr. Meshkov's supplemental opinion cannot provide a reasonable medical basis for his representation that Ms. Stone had a reduced ejection fraction.

Moreover, to the extent claimant contends that there is a reasonable medical basis for Dr. Meshkov's representation because evaluation of ejection fraction is subjective, such reliance is misplaced. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's opinion cannot be medically reasonable where the auditing cardiologist determined that claimant's echocardiogram demonstrated an ejection fraction greater than 60% and the Technical Advisor determined claimant's echocardiogram demonstrated an ejection fraction of 66%. Adopting claimant's argument would allow a claimant to recover benefits with an ejection fraction greater than the percentage defined by the Settlement Agreement and would render meaningless this critical provision of the Settlement Agreement.[9]

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8. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

9. Moreover, the Technical Advisor took into account the concept of inter-reader variability as reflected in his statement, "An echocardiographer could not reasonably conclude that an ejection fraction of 40%-49% was present on this study even taking into account inter-reader variability."

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had a reduced ejection fraction. Therefore, we will affirm the Trust's denial of Ms. Stone's claim for Matrix Benefits.